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|                         | FU DIC DATE                    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |  |
|-------------------------|--------------------------------|----------------------|------------------------|------------------|--|
| APPLICATION NO.         | FILING DATE                    | <u> </u>             | 46.US2.PCT             | 2795             |  |
| 09/762,311              | 06/25/2001                     | Marta Blumenfeld     | 46,032.1 € 1           | 2.77             |  |
| 27200                   | 7590 09/20/2002                |                      | EXAMINER               |                  |  |
| GENSET                  | a nun ID                       |                      | DAVIS, NATALIE A       |                  |  |
| JOHN LUCA<br>10665 SORR | S, PHD, J.D.<br>ENTO VALLEY RD | :                    |                        |                  |  |
| SAN DIEGO, CA 92121     |                                |                      | ART UNIT               | PAPER NUMBER     |  |
|                         |                                |                      | 1642                   | a                |  |
|                         |                                |                      | DATE MAILED: 09/20/200 | 2                |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| 3   |   | Application No.   |   | Applicant(s)   |                  |  |  |  |  |
|---|---|---|---|--|------------------|--|--|--|--|
| Office Action Summary   |   | 09/762,311  |   | BLUMENFELD ET AL.  |                  |  |  |  |  |
|   |   | Examiner  |   | Art Unit   |                  |  |  |  |  |
|   |   | Natalie A. Davis  |   | 1642   |                  |  |  |  |  |
| The MAILING DATE of   | this communication ap   | pears on the cover  | sheet with the c  | orrespondence add  | iress            |  |  |  |  |
| Period for Reply  |   |   |   |  |                  |  |  |  |  |
| A SHORTENED STATUTOR THE MAILING DATE OF TH  - Extensions of time may be available u after SIX (6) MONTHS from the mailir  - If the period for reply specified abov - If NO period for reply is specified abov - Failure to reply within the set or exten - Any reply received by the Office later earned patent term adjustment. See a | IS COMMUNICATION nder the provisions of 37 CFR 1 g date of this communication. is less than thirty (30) days, a reve, the maximum statutory period ded period for reply will, by statuthan three months after the mailing | .136(a). In no event, howe<br>ply within the statutory mini<br>d will apply and will expire S | wer, may a reply be tin<br>mum of thirty (30) day<br>SIX (6) MONTHS from<br>become ABANDONE | nely filed s will be considered timely the mailing date of this co | mmunication.     |  |  |  |  |
| 1) Responsive to comm   | unication(s) filed on <u>7</u> -  |   |   |  |                  |  |  |  |  |
| 2a) This action is FINAL.   |   | This action is non-fi   |   |  |                  |  |  |  |  |
| 3) Since this application   | is in condition for allow   | wance except for fo   | rmal matters, p   | rosecution as to th  | e merits is      |  |  |  |  |
| Disposition of Claims   | with the practice unde  |   | 1900 0.0. 11,   | 100 0.0.2  |                  |  |  |  |  |
| 4)⊠ Claim(s) <u>42-63</u> is/are  |   |   | -4:   |  |                  |  |  |  |  |
| 4a) Of the above claim  |   | rawn from consider  | ation.  |  |                  |  |  |  |  |
| 5) Claim(s) is/are  | allowed.  |   |   |  |                  |  |  |  |  |
| •   | 6) Claim(s) is/are rejected.  |   |   |  |                  |  |  |  |  |
| 7) Claim(s) is/are  | objected to.  |   |   |  |                  |  |  |  |  |
| 8)⊠ Claim(s) <u>42-63</u> are su  | bject to restriction and  | or election require   | ment.   |  |                  |  |  |  |  |
| Application Papers  |   |   |   |  |                  |  |  |  |  |
| 9) The specification is ob  | jected to by the Exami  | ner.  | ed to by the Ev   | aminer   |                  |  |  |  |  |
| 10) ☐ The drawing(s) filed or   | ıs/are: a)∐ ac  | the drawing(s) be be  | led to by the Ex  | See 37 CFR 1.85(a).  |                  |  |  |  |  |
| Applicant may not req<br>11) ☐ The proposed drawing   | uest that any objection to  | is: a)∏ approv  | ed b)∏ disapp   | roved by the Examir  | ner.             |  |  |  |  |
| 11) I he proposed drawing   | drawings are required in  | reply to this Office at   | ction.  | ·  |                  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action. 12) ☐ The oath or declaration is objected to by the Examiner.  |   |   |   |  |                  |  |  |  |  |
| ·   |   |   |   |  |                  |  |  |  |  |
| Priority under 35 U.S.C. §§ 11 13) ☐ Acknowledgment is r  | nedo of a claim for fore  | sian priority under 3   | 5 U.S.C. § 119  | (a)-(d) or (f).  |                  |  |  |  |  |
|   |   | ngh phoney and a  | • • • • • •   |  |                  |  |  |  |  |
| a) All b) Some * o  |   | ents have been rec  | eived.  |  |                  |  |  |  |  |
| <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>   |   |   |   |  |                  |  |  |  |  |
| Copies of the certified copies of the priority documents have been received in this National Stage      Copies of the certified copies of the priority documents have been received in this National Stage  |   |   |   |  |                  |  |  |  |  |
| application  * See the attached deta  | from the International filed Office action for a  | list of the certified of  | copies not recei  | ved.   |                  |  |  |  |  |
| 14) Acknowledgment is m   | ade of a claim for dom  | estic priority under  | 35 U.S.C. § 119   | e) (to a provisiona  | al application). |  |  |  |  |
| a)  The translation of 15) Acknowledgment is m  | of the foreign language   | provisional applica   | tion has been r   | eceived.   |                  |  |  |  |  |
| Attachment(s)   |   |   |   |  |                  |  |  |  |  |
| Notice of References Cited (PT 2)  Notice of Draftsperson's Patent 3)  Information Disclosure Statement   | Drawing Review (PTO-948)  | 4)<br>5)<br>5)<br>6)  | Notice of Inform  | ary (PTO-413) Paper N<br>al Patent Application (P                  | lo(s)<br>TO-152) |  |  |  |  |

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## Election/Restrictions

## **DETAILED ACTION**

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 42-57 and 59, drawn to a composition comprising nucleotide sequences of TBC-1 and a method of making a polypeptide.

Group II, claim(s) 58, drawn to a composition comprising a TBC-1 antibody.

Group III, claim(s) 60-63, drawn to a method of genotyping by determining the identity of a polymorphic base at a TBC-1-related biallelic marker.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I-III have been found by the examiner to have no special technical feature that defined a contribution over the prior art because Zon, et al., (U.S. Patent 5,700,927, 1997) teach the TBC1 gene and uses thereof. Since the inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single inventive concept and lack unity of invention.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A- biallelic marker in position 9494 of SEQ ID NO: 1
- B- biallelic marker in position 1443 of SEQ ID NO: 2
- C- biallelic marker in position 5247 of SEQ ID NO: 2

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D- biallelic marker in position 6223 of SEQ ID NO: 2

E- biallelic marker in position 14723 of SEQ ID NO: 2

F- biallelic marker in position 19186 of SEQ ID NO: 2

G- biallelic marker in position 18997 of SEQ ID NO: 2

H- biallelic marker in position 19891 of SEQ ID NO: 2

I- biallelic marker in position 29617 of SEQ ID NO: 2

J- biallelic marker in position 42519 of SEQ ID NO: 2

K- biallelic marker in position 69324 of SEQ ID NO: 2

L- biallelic marker in position 69181 of SEQ ID NO: 2

M- biallelic marker in position 69146 of SEQ ID NO: 2

N- biallelic marker in position 76458 of SEQ ID NO: 2

O- biallelic marker in position 78595 of SEQ ID NO: 2

P- biallelic marker in position 82159 of SEQ ID NO: 2

Q- biallelic marker in position 84522 of SEQ ID NO: 2

R- biallelic marker in position 84810 of SEQ ID NO: 2

S- biallelic marker in position 89967 of SEQ ID NO: 2

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In the event applicant elects claim(s) 42-57 and 59 of Group I or Claim(s) 60-3-63 of Group II, applicant is required to elect a single species of biallelic marker.

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4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f) (i) (B) (1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the polynucleotides share a common property, a biallelic marker, the polynucleotides are not regarded as being of similar nature because all the alternatives do not share a common structure.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD September 18, 2002

SHEELA HUFF
PRIMARY EXAMINER